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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EREZO, DARWIN P

ART UNIT PAPER NUMBER

3761

DATE MAILED: 01/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,922

Applicant(s)

HICKLE ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 and 80-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9, 15-26, 28, 32, 36-39, 46-66, 80-83 and 87-92 is/are rejected.
- 7) ☒ Claim(s) 10-14, 27, 29-31, 33-35, 40-45 and 84-86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1 in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 87 is constructed as a method claim which claims dependency to claim 39, which is an apparatus claim. Therefore the claim is rendered vague and indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 15, 28, 32, 36-39, 50-58, 62-65, 80-83 and 88-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al.

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6. As to claims 1-9, 15, 28, 32, 36, 50, 57, 58, 62, 63 and 80-83, Levitsky teaches a method of supplying gas to a person and sampling expired gas from the person, the method comprising: positioning an oral-nasal cannula **58** on the person in an area between a nose and a mouth of a person, the cannula having lumens **78,80** for collecting expired gases individually from the nose and the mouth, lumen **86** for providing a supplied gas for inspiration by the person having a diffuser grid **88**; collecting expired gases and analyzing the expired gas using an analyzer; wherein the supplied gas is pure oxygen; wherein the collecting lumens extend away from the diffuser; wherein the device is a pneumatic harness; wherein the lumens are capable of being separated from each other; wherein the pneumatic harness can attach to a medical device.

Levitsky is silent with regards to a lumen for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase; wherein the supplied inspired gas is a gas mixture.

Curti teaches a method of supplying gas to a person and sampling expired gas from the person comprising the steps of detecting when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase (col. 3, lines 11-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the method step of detecting when a person is inhaling or exhaling and delivering an increase flow go gas to the person during the inhalation phase, as disclosed by Curti, in the method taught by Levitsky because

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delivering gas only during the inhalation phase prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and since it is well known in the art to supply air or vaporized medicaments to a person.

7. As to claims 37-39, 55, 56, 64, 65 and 88-92, Levitsky teaches an apparatus that delivers inspired gas to a person and samples expired gases from the person, the apparatus comprising: an oral-nasal cannula **58** comprising samplers for each nare and mouth **78,80** and a diffuser grid **88**; an analyzer for detecting characteristics of the expired breath stream; wherein a CO₂ sensor is used to measure the presence of CO₂; wherein the samplers have distal ends with gas inlets at the distal ends, and wherein the gas inlets extend into expired breath airstreams of the nose and mouth and away from the diffuser grid; wherein the cannula is disposable; wherein the lumen of the diffuser grid is larger than any other lumen; wherein the device is a pneumatic harness; wherein the lumens are capable of being separated from each other; wherein the pneumatic harness can attach to a medical device.

Levitsky is silent with regards to a set of lumen for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person.

Curti teaches an oxygen delivery device for supplying gas to a person and sampling expired gas from the person comprising a set of lumens for detecting when a

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person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person; wherein an increase flow of gas is delivered during the inhalation phase (col. 3, lines 11-24); wherein the analyzer comprises capnometers (col. 2, lines 32-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the oxygen delivery device of Curti with the nasal cannula of Levitsky because the delivery means of Curti prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and since it is well known in the art to supply air or vaporized medicaments to a person.

8. As to claims 51-54, the combination of Levitsky/Curti is silent with regards to the detecting of xenon or an intravenous anesthetic. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an analyzer that can detect any substance, including xenon or an anesthetic, in order to monitor the levels of said substance during respiration.

9. Claims 16-20 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 5,626,131 to Chua et al.

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Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a pressure sensor.

Chua teaches an oxygen delivery system comprising a pressure sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Chua in the method steps taught by Levitsky/Curti because Curti teaches that the delivery system of Chua reduces the possibility of distorted carbon dioxide readings due to gas mixing (col. 3, lines 20-25).

10. Claims 21-26, 60, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 6,467,477 to Frank et al.

Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a humidity or temperature sensor.

Chua teaches an oxygen delivery system comprising a humidity or temperature sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site (col. 7, lines 19-24).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Frank in the method steps taught by Levitsky/Curti because it allows the person to control the delivery device using different sensors and different parameters.

11. Claims 46-49 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 4,602,644 to DiBenedetto et al.

Levitsky/Curti fails to teach the apparatus comprising an auditory breath sonification device, wherein the device is a microphone; wherein the person's breathing sound is simulated to distinguish between the person's inhalation and exhalation phase.

DiBenedetto teaches a nasal cannula having a microphone for amplifying a person's breathing pattern and determining a person's respiratory phase.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the microphone of DiBenedetto in the device of Levitsky/Curti because it allows a physician or caregiver to monitor the breathing of the person/patient.

Allowable Subject Matter

12. Claims 10-14, 27, 29-31, 33-35, 40-45 and 84-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe


GLENN K. DAWSON
PRIMARY EXAMINER